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AUDIT REPORT FOR SWEDEN
AUGUST 8 THROUGH 14, 2001

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Sweden's meat inspection system from August 8 through August 14, 2001. Two establishments were certified to export meat to the United States; both were audited on-site. One of these (Establishments 80) was a slaughter-and-cutting establishment; the other (Est. 455) was a cold-storage facility.

The last audit of the Swedish meat inspection system was conducted in September 2000. The same two establishments were certified to export meat to the United States and audited; both were evaluated as acceptable. The following major concerns were reported at that time:

1. Condemned materials were not denatured before being removed from the premises.

2. Documentation of corrective actions and preventive measures taken in response to sanitation problems was inadequate.

3. The HACCP program in Establishment 80 had not been adequately developed, and the documentation was deficient.

4. The Pathogen Reduction program was deficient: generic *E. coli* samples were not being collected from the ham area as required, and the establishment had not developed the required statistical process control program to evaluate the results of the *E. coli* testing.

5. The official (in-plant) inspection personnel had not received adequate training in the requirements for HACCP and Pathogen Reduction (PR), nor were they routinely monitoring the establishment's compliance the requirements of the HACCP/PR programs.

6. The performance of the inspection personnel assigned to the establishments was not being evaluated.

7. No improvements had been to correct the deficiencies that had been identified, during the previous FSIS audit, regarding the timeliness of analysis of field samples for residues or the implementation of an effective intra-laboratory check sampling program. Furthermore, meat was not being tested for mercury or arsenic residues.

At the time of this audit, only pork products were eligible for export to the United States from Sweden.

From January 1 through June 30, 2001, Sweden exported 359,932 pounds of pork cuts to the U.S. One lot (9.2% of the total) was rejected at the U.S. port-of-entry for processing defects.

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Swedish national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in the meat inspection headquarters facilities preceding the on-site visits. The third was conducted by on-site visits to establishments. The fourth was a visit to three laboratories, one performing analytical testing of field samples for the national residue testing program, and the other two culturing field samples for the presence of microbiological contamination with *Salmonella* and *E. coli*.

Sweden's program effectiveness was assessed by evaluating five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the United States. Establishment 80 fell into this category and was delisted accordingly by Sweden's meat inspection officials.

RESULTS AND DISCUSSION

Summary

Effective inspection system controls were found to be in place in Establishment 455; it was evaluated as acceptable/re-review. Establishment 80 was found to be unacceptable. Details of audit findings, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* and generic *E. coli*, are discussed later in this report.

As stated above, seven major concerns had been identified during the last audit of the Swedish meat inspection system, conducted in September-October 2000. During this new audit, the auditor determined whether these concerns had been addressed and corrected:

1. Condemned materials were not denatured before being removed from the premises. *This is a repeat deficiency from the September 2000 audit.*

2. Documentation of corrective actions and preventive measures taken in response to sanitation problems was inadequate. *This is a repeat deficiency*.

3. The HACCP program in Establishment 80 had not been adequately developed and the documentation was deficient. *Some improvement was noted, but some areas were in need of further development.*

4. The Pathogen Reduction program was deficient: generic E. coli samples were not being collected from the ham area as required. *This had been corrected; however, samples for testing for Salmonella species were now not taken from the jowl area.*

5. The establishment had not developed the required statistical process control program to evaluate the results of the E. coli testing. *This is a repeat deficiency.*

6. The official (in-plant) inspection personnel had not received adequate training in the requirements for HACCP and Pathogen Reduction, nor were they routinely monitoring the establishment's compliance the requirements of the HACCP/PR programs. *Additional training had been provided, but documentation by NFA officials of their monitoring of establishment HACCP/PR activities was deficient.*

7. The performance of the inspection personnel assigned to the establishments was not being evaluated. *This is a repeat deficiency*.

8. No steps had been taken to correct the deficiencies that had been identified, during the previous FSIS audit, regarding the timeliness of analysis of field samples for residues or the implementation of an effective intra-laboratory check sampling program. Furthermore, meat was not being tested for mercury or arsenic residues. *Improvement was seen in most turnaround times and in the majority of the intra-laboratory check sample program. Sweden had applied to FSIS for exemption from the testing requirement for mercury and arsenic and was waiting for a response; in the meantime, no testing for these heavy metals had resumed.*

The following major concerns arose as a result of this new audit (details are discussed later in the body of this report):

1. The HACCP system in Est. 80 failed to meet the basic FSIS regulatory requirements. Furthermore, the education of the in-plant inspection personnel in the principles and requirements of compliant Hazard Analysis/Critical Control Point programs and Sanitation Standard Operating Procedures was inadequate.

2. The regional reviewers, although they proved competent and well-informed regarding U.S. requirements, lacked the authority to (1) evaluate the performance of the in-plant

inspection personnel and (2) enforce the actions required to correct sanitation problems they identified during their routine internal reviews.

3. In Establishment 80, numerous deficiencies were encountered, resulting in an evaluation that controls were inadequate to meet basic FSIS requirements:
   - Post-mortem inspection procedures were inadequate.
   - Insanitary dressing resulted in contamination of the product. Corrective actions specified in the written zero-tolerance procedure were not followed.
   - Condensation was out of control, and documentation of control was inadequate.
   - Pre-operational sanitation was inadequate.
   - Personal hygiene was deficient.
   - Maintenance and cleaning of over-product equipment had been grossly neglected.
   - Lighting at post-mortem inspection stations was inadequate.

4. In the residue-testing laboratory, turnaround times for diethylstilbestrol and organophosphates were not within FSIS expectations, and no check samples had been run for chloramphenicol during the past several years.

5. Regarding the required testing programs for generic *E. coli* and *Salmonella* species:
   - Swedish officials had informed FSIS that they were using an ISO method for analysis of samples; they had changed to a Nordic Committee on Food Analysis (*Nordisk Metodikkommittee för Livsmedel, or NMKL)* method without submitting the details of the different method to FSIS for equivalence determination.
   - The sampling procedure for selecting the carcasses to be tested was not random.

6. Documentation by in-plant and supervisory NFA personnel of establishment activities was found to be inadequate in both establishments.

7. No microbiological potability testing had been performed on the water in Est. 455 since 1996.

8. No species verification was being performed as required.

Entrance Meeting

On August 8, 2001, an entrance meeting was held in the Uppsala offices of the National Food Administration *(NFA)*, and was attended by Dr. Christer Ohlsén, Department Head and Government Veterinary Inspector; Drs. Göran Mattsson and Torbjörn Axelsson, Senior Veterinary Inspectors; Drs. Peter Brådenmark and Arne Andersson, Chief Government Inspectors, Dr. PauloKisekka-Ndawula, Veterinary Inspector; and Dr. Viveka Larsson, Food Standards Department. FSIS was represented by Dr. Gary D. Bolstad, International Audit Staff Officer, hereinafter called "the Auditor," and Mr. Gary Stefan, Staff Officer, International Policy Division, Equivalence Branch, who accompanied Dr. Bolstad. Topics of discussion included the following:

1. NFA officials explained changes in the organizational structure of the organization.

2. The Auditor provided copies of the data-collection instruments that would be employed for assessing compliance with the requirements for HACCP systems, SSOPs, and testing programs for *Salmonella* species and generic *E. coli.*

3. The Auditor inquired about Sweden's residue testing results for calendar year 2000 and the 2001 residue-testing plan, neither of which had as yet been received by FSIS. The Auditor was informed that these documents had been completed as of *January 1; results--March 13.* They were offered at the entrance meeting. The FSIS auditors requested that they be forwarded directly to the Office of Policy, Program Development, and Evaluation in Washington, D.C.

4. The Auditor inquired whether the internal auditors were now empowered and instructed to evaluate the performance of the in-plant inspection personnel. The Swedish officials replied that they were not, as of the time of this meeting. They said that the internal auditors "look at" how the in-plant inspection personnel are performing, but the results are not part of the written reports. Discussions regarding the performance of the inspection personnel were all oral. A system for the documentation of evaluation of inspectors' performance was in the process of being developed, and was expected to be implemented by the end of calendar year 2001. This was of some concern, since it had been noted during the previous FSIS audit that the performance of in-plant inspection personnel was not being evaluated.

5. The Auditor provided the NFA officials with information on the U.S. port-of-entry rejections of Swedish Product for the period from January 1 to June 30, 2001.

6. The audit itinerary was discussed and finalized.

Headquarters Audit

There had been several changes in the organizational structure or upper levels of inspection staffing since the last U.S. audit of Sweden's inspection system in September 2000. A summary of the new structure was provided.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The FSIS Auditor observed and evaluated the process.

The Auditor requested a selection of inspection system documents at the headquarters of the inspection service in Uppsala. This records review focused primarily on food safety hazards and included the following:

- Training records for in-plant inspection personnel. *The Swedish officials stated that most of the in-plant officials have attended HACCP training courses at least once but that it was possible that a veterinarian newly assigned to a US-certified plant may not have had HACCP training, and it may be up to 6 months until he has that training. However, they further stated that it is up to the Veterinarian-In-Charge to assign HACCP-related duties to the NFA personnel under his supervision, and that these duties would be assigned only to those who had had the requisite training.*

- The Auditor inquired about consumer complaints and product recall actions. *The Swedish officials replied that such reports were kept in the affected establishments only and that neither copies of the reports nor statistics regarding such reports were available at NFA headquarters.*

- Animal disease status *(a summary was provided).*

- Supervisory visits to U.S. certified establishments *(several reports from these visits were available).*

- The Auditor inquired about official communications with field personnel, both in-plant and supervisory, in which U.S. requirements are conveyed. *The Swedish officials replied that Instructions were provided to in-plant personnel, but that copies of these communications were not available.*

The only concern that arose as a result the examination of these documents was that some of the requested materials were not available for examination.

Government Oversight

All inspection veterinarians and inspectors in establishments certified by Sweden as eligible to export meat products to the United States were full-time NFA employees, receiving no remuneration from either industry or establishment personnel.

Establishment Audits

Two establishments were certified to export meat products to the United States at the time this audit was conducted. Both were visited for on-site audits. NFA inspection system controls and establishment system controls in Est. 455 were found to be in place to prevent, detect and control contamination and adulteration of products. Adequate controls were found not to be in place in Est. 80, and it was delisted by the Swedish officials.

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information was also collected about the risk areas of government oversight of accredited, approved, and private laboratories; *intra*-laboratory quality assurance procedures, including sample handling; and methodology.

The laboratory of the National Food Administration, Chemistry Division in Uppsala was audited on August 13, 2001. Effective controls were in place for sample handling and frequency, data reporting, equipment operation and printouts, minimum detection levels, recovery frequency, and percent recoveries. The methods used for the analyses were acceptable. No compositing of samples was done (this was not a deficiency).

The following concerns arose as a result of the audit of this laboratory:

1. Turnaround times for diethylstilbestrol were up to 6 weeks and for organophosphates up the two months. Turnaround times of one month are expected.

2. Check samples were not performed for chloramphenicol unless a positive field sample-screening test resulted in the need for a confirmation determination; consequently, no check samples had been run for chloramphenicol during the past several years. No check samples were being run for organophosphates because the laboratory personnel "can't find a source of reference materials."

3. No corrective action reports were available for audit.

4. The following information was missing in the official standards books for the preparation of stock solutions: lot numbers, expiration dates, and the co-signature of the supervisor of the technician preparing the stock solutions.

The laboratory of the National Veterinary Institute in Uppsala was also audited on August 13, 2001. Effective controls were in place for sample handling, timely analysis, data reporting, equipment operation and printouts, minimum detection levels, and recovery frequency. The methods used for the analyses were acceptable. No compositing of samples was done (this was not a deficiency).

The following concerns arose as a result of the audit of this laboratory:

1. No samples were being run for mercury or arsenic (Sweden had applied to FSIS for an exemption from the testing requirement for these elements and was awaiting reply). No field samples from swine had as yet been tested for heavy metals (only from chickens and reindeer). Samples from swine were scheduled for later in the year (11 samples from swine and beef in week 43, and another 31 in week 45).

2. Data on percent recoveries were not available for beta-agonists.

3. Spiked samples were provided by the National Food Administration, Chemistry Division for reference. No check samples were prepared by the laboratory supervisors to test the proficiency of the analysts.

4. If an analyst did not obtain the expected results, the analysis was run again by the same analyst on a sister sample, in lieu of a documented corrective action and a resulting report.

Sweden's microbiological testing for *Salmonella* was being performed in a government laboratory in the National Veterinary Institute in Uppsala. This laboratory was audited on August 31, 2001.

One concern arose as a result of this audit: Sweden had informed FSIS that the method used for analysis for *Salmonella* species was ISO 6579; however, Sweden had changed to Nordic Committee for Food Analysis (NMKL) Method #71, and had not provided this information to International Policy Staff for an equivalence determination.

Establishment Operations by Establishment Number

The following operations were being conducted in the two establishments:

Pork slaughter, cutting and boning – Establishment 80
Cold storage – Establishment 455

SANITATION CONTROLS

Based on the on-site audits of establishments, Sweden's inspection system had controls in place for water potability records, back-siphonage prevention, hand-washing facilities, temperature control, operational and inspectors' work space, ventilation, product contact equipment, dry-storage areas, ante-mortem and welfare facilities, outside premises, personal dress and habits, and equipment sanitizing.

Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs were found to meet most of the basic FSIS regulatory requirements; however, documentation of both pre-operational and operational sanitation activities was deficient in Est. 80, and documentation of corrective actions and preventive measures was inadequate in both establishments.

The following sanitation deficiencies were found during the on-site establishment audits:

Product Handling and Storage

1. Condensation was out of control, directly above exposed product, in many areas of Establishment 80 (including the main cutting room and several carcass coolers). In spite of the condensation having been identified and discussed by both establishment and inspection officials during the audit, no effort was made either to eliminate it from above endangered product or to identify, remove, or re-inspect product stored under the problem areas.

2. In the "U.S. Pack Room" in Est. 80, carton liners ready for use were stored in contact with dirty chemical containers in an unclean container. A management representative removed the chemicals and brought new liners.

Pre-Operational Sanitation (Est. 80)

1. Pre-operational sanitation in the large cutting room was inadequate. Product residues from the previous day's production were found on product contact surfaces and floor mats were placed on cleaned boning table surfaces that would be used for plastic containers of edible product. Inspection personnel ordered the product-contact equipment to be re-cleaned twice before operations were allowed to begin.

2. Product was brought into the main cutting room to start operations after pre-operational sanitation had been determined to be inadequate and before the area had been passed for operations to begin.

Personal Hygiene (Est. 80)

1. Upon entering production areas for the audit of pre-operational sanitation verification, neither establishment officials nor inspection officials washed their hands until the Auditor pointed out the need.

2. Many (more than thirty) instances of deficient personal hygiene (e.g., employees wiping noses with product-contact gloves, picking up dropped meat from the floor and going back to work without changing gloves or washing hands) were observed throughout the day.

Dressing Procedures (Est. 80)

The exposed anuses of slaughtered swine (no protective plastic bung bags were used) were observed to contact the meat surfaces of the carcasses during the viscera-dropping operation. The operator did not identify the carcasses for segregation and trimming as required in the written zero-tolerance procedure. The same operator was observed to routinely contact the meat surfaces of carcasses after handling the exposed anus, without washing his hands.

Facilities and Equipment (Est. 80)

1. Maintenance and cleaning of over-product equipment had been grossly neglected in many production areas. Heavy accumulations of rust, dust, flaking paint, and old product residues and scraps were observed. In one problem area, where a drip in the space above a carcass load-out room was splashing through a large opening in the ceiling that contained a very dusty grid, product was placed directly under the unclean splash that had been identified and discussed only minutes before. In the "U.S. Packing Room," old, rusty, open-ended pipes projected down through the ceiling, and a rusty and dusty fan was in use, directly above exposed product.

2. Obvious heavy accumulations of a white, granular substance (presumably, in the opinion of the Swedish officials, cleaning chemicals from rooms above) had leaked through large cracks in ceilings directly above exposed product and product traffic areas.

3. Waste containers throughout the establishment had hand-operated lids.

Pest Control

In Est. 455, two bait stations around the outside perimeter, very close to an adjacent river, contained bait blocks that showed obvious signs of rodent activity. There was a history of activity in bait stations in this area. Also, much debris (old pallets, discarded machinery and equipment, pipes, etc) was stored close to an outside wall, very near an adjacent river, and in close proximity to the bait stations where rodent activity had been noted. The NFA officials ordered prompt correction.

Water Potability

The management officials in Est. 455 stated that they had been informed, by an official State Veterinarian, that water potability testing was not required because there was no exposed product in the establishment. No microbiological potability testing had been performed since 1996.

ANIMAL DISEASE CONTROLS

Sweden’s inspection system had controls in place to ensure adequate animal identification and procedures for sanitary handling of returned and rework product. There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit.

The following deficiencies were identified in Est. 80:

1. Lighting at post-mortem inspection stations was inadequate. A minimum of fifty foot-candles (fc) of shadow-free light is required; 20 fc were measured at mandibular lymph nodes and 30 fc in abdominal cavities.

2. Incisions in mandibular lymph nodes were inadequate. One inspector was observed to incise salivary glands, leaving the lymph nodes intact. Inspectors were not adequately observing the cut surfaces of the lymph nodes they had incised. These deficiencies had also been identified and documented by one of the Swedish internal reviewers during a routine review of the establishment the previous June.

RESIDUE CONTROLS

The Swedish inspection system had adequate controls in place to ensure compliance with residue sampling and monitoring procedures, sample handling, data reporting procedures, recovery frequency, percent recoveries, and approval and use of chemicals in the establishments. All analysts participated in the check sample programs.

Sweden's National Residue Testing Plan for 2000 was being followed, and was on schedule. No field samples from swine had as yet been requested for analysis for diethylstilbestrol; they were scheduled for autumn. (It was noted that 85 samples from beef were scheduled to be sampled in 2001; all had been received and analyzed.) Also, no field samples from swine had as yet been tested for heavy metals (only from chickens and reindeer). Samples from swine were scheduled for later in the year (11 samples from swine and beef in week 43, and another 31 in week 45).

The following observations were noted:

1. No samples were being run for mercury or arsenic. (Sweden had applied to FSIS for an exemption from the testing requirement for these elements and was awaiting reply.)

2. Turnaround times (the length of time between a sample's arrival in the laboratory and the completion of its analysis) for diethylstilbestrol were up to 6 weeks and for organophosphates up to two months. Turnaround times of one month are expected.

3. Check samples were not performed for chloramphenicol unless a positive field sample-screening test resulted in the need for a confirmation determination; consequently, no check samples had been run for chloramphenicol during the past several years. No check samples were being run for organophosphates because the lab "can't find a source of reference materials."

4. No check samples for heavy metals were prepared by the laboratory supervisors to test the proficiency of the analysts. Spiked samples were provided by the National Food Administration, Chemistry Division for reference.

5. If an analyst did not obtain the expected results for an arsenic analysis, the analysis was run again by the same analyst on a sister sample, in lieu of a documented corrective action and a resulting report. No corrective action reports were available for audit in the NVA Chemistry Division Laboratory.

6. Data on percent recoveries were not available for beta-agonists.

7. The following information was missing in the official standards books for the preparation of stock solutions: lot numbers, expiration dates, and the co-signature of the supervisor of the technician preparing the stock solutions.

8. There was no separate room for the storage of cleaning chemicals in Est. 455. The NFA official ordered prompt correction.

SLAUGHTER/PROCESSING CONTROLS

The Swedish inspection system had controls in place to ensure adequate humane handling and slaughter, pre-boning trim, packaging materials, label approvals, and processing equipment.

No chemical or physical denaturing of condemned products was performed as required. This was a repeat deficiency from the September 2000 audit.

HACCP Implementation

All slaughter and processing establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. The system in Est. 80 was evaluated according to the criteria employed in the U.S. domestic inspection program and was found to fail to meet the basic FSIS regulatory requirements. The data collection instrument used accompanies this report (Attachment B):

1. Information contained in pre-shipment document reviews was inadequate.

2. The monitoring frequency for one Critical Control Point was not indicated in the written HACCP plan.

Testing for Generic *E. coli*

According to information provided by the Swedish officials to FSIS, Sweden had adopted the FSIS regulatory requirements for E. coli testing. Establishment 80 was required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and was audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C). The following deficiencies were found:

1. The sampling procedure for selecting the carcasses to be tested for generic *E. coli* was one of convenience, rather than following a random procedure, as required.

2. The establishment employee sampling carcasses for generic *E. coli* was observed to contaminate the inside of the sterile bag for the swab with her (ungloved) hand.

3. The establishment had not developed a statistical process control method for evaluating the results of the swabbing-method generic *E. coli* testing procedure as required. Instead, the criteria reserved for the excision method were being applied.

ENFORCEMENT CONTROLS

Inspection System Controls

The NFA inspection system controls were in place and effective in ensuring that products produced by the establishment were properly labeled. In addition, adequate controls were found to be in place for control of restricted product and inspection samples, boneless meat reinspection, shipment security, including shipment between establishments. Furthermore, controls were adequate for security items, and products entering the establishments from outside sources. Also, both establishments had adequate controls in place to prevent meat products intended for Swedish domestic consumption from being commingled with products eligible for export to the U.S. No livestock was imported from other countries for slaughter, and no meat slaughtered at other Swedish establishments was received by Est. 80.

Documentation by in-plant and supervisory NFA personnel of establishment activities was found to be inadequate in both establishments.

Testing for *Salmonella* Species

Establishment 80 was required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

According to information provided by the Swedish officials to FSIS, Sweden had adopted the FSIS regulatory requirements for HACCP. *Salmonella* testing was reported to be the same with exception of the following equivalent measures:

1. SALMONELLA TESTING STRATEGY.

    - Sweden uses a continuous, ongoing sampling program to determine when to initiate additional *Salmonella* testing. All U.S. export establishments are included in the sample pool. The Swedish Performance Standards and enforcement procedures are stricter than FSIS requirements and are applied uniformly to all applicable export establishments. The sampling program is based on each establishment's production, with a minimum of one sample per production day (large and small establishments) or one sample per week (small establishments). If one positive is found during the ongoing program, Sweden requires the establishment to take corrective action and

immediately initiates a second sample set. The second set consists of 59 samples taken during the first 5 consecutive workdays (after confirmation of the positive), and continues at a rate of one sample per day for an additional 50 days of production (for swine). If a positive is found during the second sample set, the establishment is removed from the list of approved export establishments.

- Sweden requires year-round continuous *Salmonella* sampling of all products for which there is a U.S. performance standard.

- Sweden's testing program has statistical criteria for evaluating the test results.

- The percentage of *Salmonella* positives over time meets the FSIS performance standard.

2. SAMPLING TOOLS.

- The swab method of sample collection is used. The swab tool is an internationally recognized sample collection tool for sampling *Salmonella* on meat or poultry surfaces.

- The swab is sensitive enough to gather an adequate quantity of the *Salmonella* that are present at the sample sites.

- The swab does not contaminate the surfaces of the carcass.

3. SAMPLING TECHNIQUES: Time of collection of samples.

- Samples are taken at the end of the slaughter or production process.

- Samples are taken prior to the carcass being cut and/or packaged.

4. SAMPLING TECHNIQUES: Moistening agents for sponges.

- Prior to sampling, 10 ml of Phosphate Buffered Water (PBW) is added to moisten the swab. The use of PBW as a moistening agent for the sampling tool will not affect the outcome of the analysis as long as Buffered Peptone Water is used during the pre-enrichment step at the laboratory. At the laboratory, the swabs are completely submerged in the pre-enrichment broth to allow for growth of all *Salmonella* that are present. The additional volume of BPW is not critical when using a qualitative method of analysis.

5. SAMPLING TECHNIQUES: Compositing samples.

- Samples are composited at the laboratory rather than at the establishment.

- All of the sampling sites designated in the PR/HACCP final rule, or equivalent sampling sites, are included in the analysis.

6. ANALYTICAL METHODS: Different methods.

- The laboratories use ISO 6579 to analyze for *Salmonella*. ISO 6579 is an internationally recognized method of analysis for detecting *Salmonella* and is closer to the FSIS method than the AOAC methods.

7. ANALYTICAL METHODS: Amount of buffered peptone water.

- 100 ml of Buffered Peptone Water (BPW) is added to the two swabs. The swabs are completely submerged in BPW.

8. LOCATION AND SIZE OF SAMPLE SITES. Location of sample sites; Size of sample sites.

- Sweden collects samples from two large sites. These two sites include the sample collection areas from all three FSIS sample sites or their equivalent.

- The sample sites encompass a large enough surface area to ensure that the effectiveness of HACCP plans can be evaluated.

- The two sample sites provide the same probability of detecting the presence of *Salmonella* as the FSIS sample sites.

The on-site verification by the Auditor of this information revealed the following discrepancies:

1. Carcass selection for microbiological sampling for *Salmonella* was not random, but was a procedure of convenience.

2. The jowl was not swabbed for *Salmonella* testing as required.

3. Sweden had informed FSIS, as stated above, that the method used for analysis for *Salmonella* species was ISO 6579; however, Sweden had changed to Nordic Committee for Food Analysis (NMKL) Method #71, and had not provided this information to International Policy Staff for an equivalence determination.

<u>Species Verification</u>

At the time of this audit, Sweden was not exempt from the species-verification requirement; however, no species verification was being performed, either in the slaughter establishment or in the cold storage facility. The author advised the Swedish officials of the requirement

and suggested that, before a new slaughter establishment is certified as eligible for U.S. export, or before Est. 80 is re-certified, they apply for an exemption from the species verification requirement, provided they are able to meet the criteria.

Monthly Reviews

The supervisory visits were being performed by the 4 Regional Governmental Veterinary Inspectors and two other Senior Veterinary Inspectors assigned to NFA Headquarters. All were veterinarians, employed by NFA. All had received HACCP-PR training and other instruction regarding US requirements and had a minimum of several years of field experience. By the end of 2001 all were expected to have certification as ISO-9000 auditors. Internal auditors stayed up-to-date on US requirements through weekly internal staff meetings, in which field personnel participated by phone, as well as semiannual seminars. Their supervisor was Dr. Christer Olsén, Coordinator for Inspection and Coordination.

Routine reviews were announced to establishment management officials about a week in advance. In the event of problems that indicate a need for an extra visit, establishment personnel might or might not be informed in advance, depending on the nature of the problem.

The reviews were usually conducted by a single auditor, but sometimes by two; occasionally their supervisor accompanied the reviewer(s). Records of audited plants were kept on file both in NFA central offices and in the individual establishments, and were maintained indefinitely.

Significant problems encountered during a routine audit must be addressed by establishment management officials in writing to NFA and followed up by the in-plant NFA personnel.

In the event that an establishment is determined by an internal reviewer to be unacceptable, the reviewer would notify Dr. Olsén, who would then undertake the necessary actions (withdrawal of U.S. stamps and seals). If a plant is found to be out of compliance with US requirements during an audit, a delistment notice is provided to the U.S. Embassy in Stockholm within 48 hours.

The Auditor found that the audits of the establishment facilities and processes led by NFA officials to be thorough and complete. However, it is a matter of considerable concern that these internal reviewers were neither authorized nor instructed to review and evaluate the performance of the inspection personnel assigned to duties in the establishments.

An audit of the in-plant documentation showed that there had been no supervisory reports for November 2000 or March 2001 in Est. 80, and none during the months of November and December 2000 in Est. 455.

Enforcement Activities

During the entrance meeting, the Auditor inquired about consumer complaints and product recall actions. The Swedish officials replied that such reports were kept in the affected establishments only and that neither copies of the reports nor statistics regarding such reports were available at NFA headquarters. The Auditor also asked about official communications with field personnel, both in-plant and supervisory, in which U.S. requirements are conveyed. The Swedish officials replied that Instructions were provided to in-plant personnel, but that copies of these communications were not available.

The auditor informed the Swedish meat inspection officials that a major emphasis would be placed upon enforcement controls, their documentation, and the availability of that documentation to FSIS auditors, during the routine audit to be conducted in fiscal year 2002.

Exit Meetings

An exit meeting was conducted in Uppsala on August 14, 2001. The Swedish participants were Dr. Christer Ohlsén, Department Head and Government Veterinary Inspector; Drs. Göran Mattsson, Torbjörn Axelsson, and Klas Svensson, Senior Veterinary Inspectors; Drs. Peter Brådenmark and Arne Andersson, Chief Government Inspectors, Dr. Paulo Kisekka-Ndawula, Veterinary Inspector; Dr. Gunnel Alfredsson, Senior Chemist Drs. Lars Jorhem and Bengt-Göran Österdahl, Chemistry Divisions 1 and 2, respectively; Dr. Mikael Hederland, Dept. of Chemistry, National Veterinary Institute, and Dr. Viveka Larsson, Food Standards Department. FSIS was represented by Dr. Gary D. Bolstad, International Audit Staff Officer, and Mr. Gary Stefan, International Policy Staff Officer, Equivalence Branch. Ms. Lana Bennett, Agricultural Counselor in the U.S. Embassy in Stockholm, was also present. The following topics were discussed:

The findings in the two establishments were discussed in detail. The Swedish officials gave assurances that, in Est. 455, all the deficiencies would be promptly corrected. They gave further assurances that, if/when the management of Est. 80 should wish to have the establishment reinstated for U.S.-export eligibility, all the deficiencies identified would be addressed and corrected.

CONCLUSION

The two establishments certified by the Swedish National Food Administration were audited. Establishment 455, a cold-storage facility, was found acceptable/re-review; Establishment 80, a slaughter/cutting/boning operation, was evaluated by the Swedish officials as unacceptable. The inspection system of Sweden was found to have deficiencies that called into question the effectiveness of controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments. The major concerns included inadequate oversight of both establishment and in-plant inspection controls; inadequate development, implementation, and

documentation of HACCP requirements; inadequate education of field personnel in the principles and monitoring of HACCP programs; numerous sanitation deficiencies; no denaturing of condemned materials; deficiencies in the implementation of the pathogen reduction program; and lack of a species verification program. These deficiencies were discussed in detail, both during establishment and laboratory visits and in the exit meeting in Uppsala. The Swedish officials gave assurances that they understood the requirements and that they would ensure that they would be developed, implemented, and documented as required in any establishment before it would be certified as eligible to export to the United States.

Dr. Gary D. Bolstad *(signed) Dr. Gary D. Bolstad*
International Audit Staff Officer

ATTACHMENTS

A. Data collection instrument for SSOPs
B. Data collection instrument for HACCP programs
C. Data collection instrument for *E. coli* testing
D. Data collection instrument for *Salmonella* testing
E. Laboratory Audit Forms
F. Individual Foreign Establishment Audit Forms
G. Written Foreign Country's Response to the Draft Final Audit Report

Attachment A

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Fre-quency addressed	6. Respons-ible indiv. identified	7. Docu-mentation done daily	8. Dated and signed
80	√	√	√	√	√	√	Inadeq.	√
455	√	√	√	N/A	√	√	Inadeq.	√

Attachment B

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. (except Est. 12, which was a cold-storage facility) was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment has conducted a hazard analysis that includes food safety hazards likely to occur.
3. The analysis includes the intended use of or the consumers of the finished product(s).
4. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
5. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
6. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
7. The plan describes corrective actions taken when a critical limit is exceeded.
8. The HACCP plan was validated using multiple monitoring results.
9. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
10. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
11. The HACCP plan is dated and signed by a responsible establishment official.
12. The establishment is performing routine pre-shipment document reviews.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis conducted	3. Use & users included	4. Plan for each hazard	5. CCPs for all hazards	6. Monitoring is specified	7. Corr. actions are described	8. Plan validated	9. Adequate verific. procedures	10.Adequate documentation	11. Dated and signed	12.Pre-shipmt. doc. review
80	√	√	√	√	√	√	√	√	√	√	√	inadeq.

Attachment C

Data Collection Instrument for Generic *E. coli* Testing

Each establishment (except Est. 12, which was a cold-storage facility) was evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written procedure for testing for generic *E. coli.*
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is/are being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. #	1.Written procedure	2. Sampler designated	3.Sampling location given	4. Predomin. species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
80	√	√	√	√	√	√	no	no	√	√

Attachment D

Data Collection Instrument for *Salmonella* testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. Salmonella testing is being done in this establishment.

2. Carcasses are being sampled.

3. Ground product is being sampled.

4. The samples are being taken randomly.

5. The proper carcass site(s) and/or collection of proper product (carcass or ground) is being used for sampling.

6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. #	*1. Testing as required*	*2. Carcasses are sampled*	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
80	√	√	N/A	no	no	N/A